PMI PEPIN MANUFACTURING INC.

K070807

510(k) Summary

MAY 23 2007

Company Name: Pepin Manufacturing, Inc.
1875 Highway 61 South
Lake City, MN 55041

Contact: Jeff Solberg, President
Phone: 651 345-5655
Fax: 651 345-5656

Summary Date: May 1, 2007

Trade Name: Cutaneous Electrotherapy and Recording Electrodes; TENS Electrodes

Common Name: Cutaneous electrode;
Accessory TENS Electrode to Transcutaneous electrical nerve stimulator (TENS) for pain relief

Classification Name: 21 CFR 882.1320, Cutaneous Electrodes

21 CFR 882.5890 Transcutaneous Electrical Nerve Stimulators for Pain Relief

Predicate Device(s):

510(k) Number: K932849
Manufacture: Pepin Manufacturing Incorporated
Trade Name: PMI TENS Electrodes

510(k) Number: K010431
Manufacture: Lead-Lok
Trade Name: Lead-Lok Reusable TENS/NMES Electrodes

510(k) Number: K983097
Manufacture: Uni-Patch, Inc.
Trade Name: TENS/FES/FMES Electrodes

510(k) Number: K023347
Manufacture: Chattanooga Group
Trade Name: Vital Stim Electrodes

1.0 Description of Electrodes

Pepin Manufacturing Incorporated (PMI) has a 510(k) clearance for TENS Electrodes, reference 510(k) K932849. This 510(k) submission addresses two modifications to these electrodes:

1) Sterile TENS electrodes variation will be commercially available.
2) Use of these TENS electrodes as cutaneous electrotherapy electrodes consistent with the cutaneous electrode classification, 21 CFR 882.1320: "A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation."

The electrodes described by this 510(k) submission remain single patient use devices. The electrodes provide the patient contact device when connected to commercially available electrotherapy (electrical stimulation) and recording devices.

2.0 Intended Use of Electrodes

The indication for use of the cutaneous electrotherapy and recording electrodes is consistent with the classification of cutaneous electrodes 21 CFR 882.1320: "A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation." and predicate cutaneous electrodes. The indication for use is:

The Pepin Manufacturing, Inc. cutaneous electrotherapy and recording electrodes are intended to be used to apply electrical stimulation current to the patient's skin or record physiological signals.

Example electrical stimulation current applications of these electrodes are:

a) Transcutaneous Electrical Nerve Stimulation (TENS) for pain relief.
b) Electrical muscle stimulation (EMS); Powered Muscle Stimulators.
c) Functional electrical stimulation (FES).
d) Galvanic stimulation.
e) Microcurrent electrical nerve stimulation (MENS).
f) Interferential stimulation.
g) Neuromuscular electrical stimulation (NMES).

3.0 Technological Characteristics

The cutaneous electrotherapy and recording electrodes do not contain active electronics, software or firmware. The cutaneous electrotherapy electrodes connect to the user's electronic device. The electrode construction is equivalent to the predicate devices.

4.0 Conclusions

The Pepin Manufacturing, Inc. cutaneous electrotherapy and recording electrodes are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Quality & Regulatory Associates, LLC
% Mr. Gary Syring
Principal Consultant
800 Levanger Lane
Stoughton, Wisconsin 53589

MAY 23 2007

Re: K070807
Trade/Device Name: Cutaneous electrotherapy and recording electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrodes
Regulatory Class: Class II
Product Code: GXY
Dated: May 10, 2007
Received: June 9, 2007

Dear Mr. Syring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

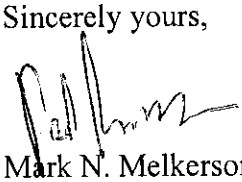
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070807

Device Name: Cutaneous Electrotherapy and Recording Electrodes

Indications for Use:

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f) Interferential stimulation.

g) Neuromuscular electrical stimulation (NMES).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

10/08/07